Application No.: 10/734,562 Attorney Dkt. No.: USGINZ02512

Examiner: Dornbusch, Dianne

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application. Where claims have been amended, deletions are indicated by strikethrough, and additions are indicated by underlining:

In the claims:

1. – 20. (Cancelled).

21. (Currently Amended) A method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy, the method comprising:

advancing an overtube comprising a plurality of nested elements having mating contoured surfaces within the hollow body organ in a flexible state;

transitioning the overtube to a rigid state by imposing a load that clamps the contoured surfaces of adjacent nested elements together to thereby substantially fix the shape of the overtube in any desired configuration;

advancing a plication device through <u>a lumen defined by</u> the overtube after the overtube has been transitioned to the rigid state, the plication device comprising a pair of <u>movable jaws adapted to engage tissue within the hollow body organ;</u> and

forming a tissue fold within the hollow body organ with the plication device.

- 22. (Original) The method of claim 21 further comprising visualizing formation of the tissue fold.
- 23. (Original) The method of claim 22, wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element advanced through the overtube.

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24. (Original) The method of claim 22, wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element coupled to the overtube.

- 25. (Original) The method of claim 21, wherein the medical procedure comprises endoscopically treating gastroesophageal reflux disease, advancing the overtube within a hollow body organ comprises advancing the overtube through a patient's esophagus and into the patient's stomach, transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a configuration enabling access to the patient's gastroesophageal junction, and forming a tissue fold comprises forming at least one tissue fold in a vicinity of the patient's gastroesophageal junction.
- 26. (Original) The method of claim 21, wherein the medical procedure comprises endoscopically performing gastric reduction, advancing the overtube within a hollow body organ comprises advancing an overtube through a patient's esophagus and into the patient's stomach, transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a desired configuration within the patient's stomach, and forming a tissue fold comprises forming a plurality of tissue folds within the patient's stomach.
- 27. (Original) The method of claim 26 further comprising approximating and securing the plurality of tissue folds, thereby partitioning the patient's stomach into at least first and second chambers over at least a portion of the stomach.
- 28. (Original) The method of claim 26, wherein forming, approximating and securing a plurality of tissue folds further comprises: forming, approximating and securing a first plurality of tissue folds in a first plane; and forming, approximating and securing at least one additional plurality of tissue folds in at least one additional plane, wherein the first plane and the at least one additional plane are substantially parallel to one another.

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29. (Original) The method of claim 27, wherein partitioning the stomach into first and second chambers further comprises partitioning the stomach into a first lumen and a second chamber.

- 30. (Original) The method of claim 29, wherein partitioning the stomach into a first lumen and a second chamber further comprises partitioning the stomach such that the patient's gastroesophageal junction only communicates with the first lumen.
- 31. (Original) The method of claim 30, wherein partitioning the stomach into a first lumen comprises partitioning the stomach into a first lumen having a volume in the range of 10-50 cm³.
- 32. (Original) The method of claim 26, wherein forming a plurality of tissue folds further comprises forming a plurality of tissue folds inferior to the patient's gastroesophageal junction.
- 33. (Original) The method of claim 32, wherein forming a plurality of tissue folds further comprises forming a plurality of tissue folds having at least one tissue fold from an anterior segment of the patient's stomach and at least one tissue fold from an opposing posterior segment of the patient's stomach.
- 34. (Original) The method of claim 26, wherein forming a plurality of tissue folds within a patient's stomach comprises forming and securing a plurality of tissue folds disposed at substantially randomly selected locations to reduce a volume of the stomach.
- 35. (Original) The method of claim 26, wherein forming a plurality of tissue folds within a patient's stomach comprises forming a plurality of interconnected tissue folds around a perimeter of the patient's stomach with instruments advanced through, or coupled to, the overtube, the method further comprising approximating the plurality of interconnected tissue folds to remodel the stomach to an hourglass profile.

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36. (Original) The method of claim 21, wherein the medical procedure comprises resecting a lesion or cancer within a patient's gastrointestinal tract, advancing the overtube within a hollow body organ comprises advancing the overtube through the patient's esophagus or colon, transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a configuration enabling access to the lesion or cancer, and forming a tissue fold comprises forming at least one tissue fold with a plication device advanced through, or coupled to, the overtube, so that the lesion or cancer is disposed on the tissue fold.

- 37. (Original) The method of claim 36 further comprising removing the lesion or cancer.
- 38. (Original) The method of claim 37, wherein removing the lesion or cancer further comprises removing the lesion or cancer with cutting apparatus.
- 39. (Original) The method of clalm 38, wherein removing the lesion or cancer with cutting apparatus further comprises removing the lesion or cancer with a snare.
- 40. (Original) The method of claim 21, wherein the medical procedure comprises endoscopically treating a bleeding site within a patient's gastrointestinal tract, advancing the overtube within a hollow body organ comprises advancing the overtube through the patient's esophagus or colon, transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a configuration enabling access to the bleeding site, and forming a tissue fold comprises forming at least one tissue fold with a plication device advanced through, or coupled to, the overtube, so that the bleeding site is disposed on the tissue fold.
- 41. (Original) The method of claim 40 further comprising securing the tissue fold, thereby reducing bleeding from the bleeding site.

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42. (Original) The method of claim 41, wherein securing the tissue fold further comprises securing the tissue fold with an anchor assembly.

43. (Currently Amended) A method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy, the method comprising:

advancing a main body within the hollow body organ in a flexible state, the main / body having a plication device coupled to extendable from a distal region thereof, the main body comprising a plurality of nested elements having mating contoured surfaces, and the plication device comprising a tissue grabbing assembly a pair of movable jaws adapted to engage tissue within the hollow body organ and a flexible tube containing one or more tissue anchors:

transitioning the main body to a rigid state by imposing a load that clamps the contoured surfaces of adjacent nested elements together to thereby substantially fix the shape of the overtube in any desired configuration; and

forming a tissue fold within the hollow body organ with the plication device.

- 44. (Original) The method of claim 43 further comprising visualizing formation of the tissue fold.
- 45. (Original) The method of claim 44, wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element advanced through the overtube.
- 46. (Original) The method of claim 44, wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element coupled to the overtube.
- 47. (Currently Amended) The method of claim 43, wherein the medical procedure comprises endoscopically treating gastroesophageal reflux disease, advancing the main body within a hollow body organ comprises advancing the main body having a

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plication device coupled to extendable from a distal region thereof through a patient's esophagus and into the patient's stomach, transitioning the main body to a rigid state comprises transitioning the main body to a rigid state in a configuration that provides for engagement of tissue in a vicinity of the patient's gastroesophageal junction with the plication device, and forming a tissue fold comprises forming at least one tissue fold in the vicinity of the patient's gastroesophageal junction.

- 48. (Currently Amended) The method of claim 43, wherein the medical procedure comprises endoscopically performing gastric reduction, advancing the main body within a hollow body organ comprises advancing a main body having a plication device eoupled to extendable from a distal region thereof through a patient's esophagus into the patient's stomach, transitioning the main body to a rigid state comprises transitioning the main body to a rigid state in a desired configuration within the patient's stomach, and forming a tissue fold comprises forming a plurality of tissue folds within the patient's stomach.
- 49. (Original) The method of claim 48 further comprising approximating and securing the plurality of tissue folds, thereby partitioning the patient's stomach into at least first and second chambers over at least a portion of the stomach.